

## REMARKS

### FORMAL MATTERS:

With entry of this paper, claims 38-40 and 56-75 are pending.

Claims 1-37 and 41-55 have been canceled.

Withdrawn claims 1-15, 30-37 and 41-55 are canceled without prejudice with this amendment.

Applicant reserves the right to include canceled claims of this application in one or more divisional applications pursuant to 35 U.S.C. §121.

New claims 56-75 have been added with this amendment.

Claims 38-40 have been examined and stand rejected.

Applicant respectfully requests entry of the amendment presented as to claim 38. The amendment is made to clarify the nature of the invention. Support for new claims 56-74 and the amendment to claim 38 may be found throughout Applicant's specification, for example in paragraph [0108], figures 19, 20 and 22, and the original claims to Applicants invention. Support for claim 75 may further be found in paragraph [0122] of Applicant's disclosure. No new matter is added with entry of the amendments and new claims contained herein.

### REJECTIONS UNDER §112, ¶2

Claims 38-40 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the invention. Clarification is requested regarding the phrase "a suture or a band of material." The Office Action indicates that it is unclear which recitation the applicant wishes to keep and which should have been deleted.

Applicants respectfully maintain that the claims as written satisfies the requirements of 35 U.S.C. §112, second paragraph. Applicant is entitled to claim what he regards as his invention, unless the subject matter lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Applicant's specification identifies a "suture" and a "band of material" as interchangeable for the purposes stated (E.g., paragraph [0106]). As such, unity of invention exists in the claim as written, and should be examined as such. *In re Weber*,

580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978). Accordingly, Applicant respectfully requests the rejection be withdrawn.

The Office Action identifies Applicant's Claim 40 as reciting the limitation "the atrium" in line 2. According to the Office, there is insufficient antecedent basis for this limitation in the claim. Applicant disagrees, but in the interest of cooperation and expeditious prosecution, Applicant has amended claim 40 to "an atrium" to extinguish all confusion. In view of the amendment, Applicant respectfully requests the instant rejection be withdrawn.

### **REJECTIONS UNDER §102**

Claims 38-40 are rejected under 35 U.S.C. §102(b) as being anticipated by Sterman *et al.* (USP 5,814,097). Applicant respectfully traverses the rejection.

In order to anticipate Applicant's invention, a prior art document must contain all of the elements and limitations of the Applicants' rejected claim(s). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genetech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Applicant respectfully submits that Sterman cannot anticipate Applicant's invention because Sterman does not teach "a plurality of plication staples suitable for application to a mitral valve annulus" or "a suture or a band of material adapted to be stapled to a mitral valve annulus at fixed positions along the suture or band of material to plicate mitral valve annulus tissue and thereby reduce the length of the mitral valve annulus" as recited in Applicant's amended claims.

The Office Action characterizes Sterman et al as disclosing in figures 8-9, a system for performing annuloplasty (see col. 27, lines 14-23), including: a plurality of staples (see col. 27, line 42), a suture 198 is able to staple to a mitral valve annulus along the suture to plicate mitral valve annulus which is able to reduce the length of the valve annulus (see col. 22, lines 58-67). Applicant respectfully submits that this is an incorrect reading of the reference as cited. Referring first to the passage at col. 22, Sterman reads:

"Various types of stitches may be used in applying sutures 198 to valve annulus VA. In an exemplary embodiment, a "mattress" suture technique is used, wherein each needle 200 is driven through valve annulus VA from the ventricular side toward the atrial side of valve annulus VA. Alternatively, an "everting mattress" suture technique is used, wherein each needle 200 is driven through valve annulus VA from the atrial side toward the ventricular side of valve annulus VA. Various other types of stitches may also be used, depending upon the type of replacement valve to be utilized and the position in which it is to be mounted to valve annulus VA."

Sterman at Col. 22, line 58 *et seq.* (emphasis added)

Nowhere does Sterman discuss "a plurality of plication staples suitable for application to a mitral valve annulus." Sterman makes no mention of the use of staples of any kind in repairing a mitral valve. In fact, Applicant respectfully submits the passage quoted from Sterman has nothing to do with repairing an existing valve *in situ*, as contemplated for Applicant's invention. Sterman is referring to insertion of an artificial replacement valve after removal of the patient's own mitral valve.

The Office relies on a passage from Sterman col. 27 for support of the use of staples. Applicant respectfully submits that this reliance is also misplaced. Referring to col. 27:

"When the valve replacement or other surgical procedure in left atrium LA is completed, atriotomy 162 is closed. Sutures, thoracoscopic staples or other types of closure devices may be used for this purpose."

Sterman at Col. 27, lines 41-44. (emphasis added)

The cited passage refers to closing the wound in the wall of the atrium **after the valve replacement is completed**. The passage has nothing to do with *in situ* repair of a valve defect by shortening the mitral valve annulus using staples suitable for such purpose and consequently thoracoscopic staples cannot be construed as suitable for application to a mitral valve annulus of a beating heart, as required by Applicant's claims. Therefore Sterman fails to teach all elements of Applicant's claims as amended and cannot anticipate.

Finally, Applicant respectfully points out that the Sterman disclosure expressly states that the device(s) discussed are for use on an arrested heart (see, e.g., Sterman Abstract). In contrast, Applicant's claimed invention is designed for use on a beating heart, providing the added advantage that the patient's heart need not be arrested to undergo surgical implantation and therefore the use of a heart-lung replacement during surgery is not necessary. Applicant respectfully submits the structural features necessary to provide such functionality are part of Applicant's pending claims, and are not anticipated by Sterman. Accordingly, Applicant respectfully requests the rejection as to Sterman be withdrawn.

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

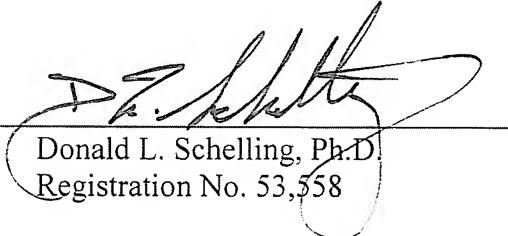
The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UOMB-001DIV.

Should the Examiner feel that a telephonic interview or other clarification would be helpful, the undersigned is available at 650-833-7740 at the Examiner's pleasure.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: May 24<sup>th</sup>, 2007

By:



Donald L. Schelling, Ph.D.  
Registration No. 53,558

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, California 94303  
Telephone: (650) 327-3400  
Facsimile: (650) 327-3231